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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,691	03/08/2004	Marc Bellotti	44378/293531 (13131-0331)	6082
23370	7590	01/26/2005	EXAMINER	
JOHN S. PRATT, ESQ KILPATRICK STOCKTON, LLP 1100 PEACHTREE STREET ATLANTA, GA 30309			MONDESI, ROBERT B	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Office Action Summary</p>	Application No. 10/796,691	Applicant(s) BELLOTTI ET AL.	
	Examiner Robert B Mondesi	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) 25-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>March 08, 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election of Invention I, **claims 1-24**, in response to the restriction requirement mailed November 29, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The examiner would like to clarify that the pending claims are **claims 1-72** and that **claim 72** is in Group XI. **Claims 1-24** are presently under examination.

Priority

The current application filed on March 08, 2004 claims priority to provisional application 60/484,690 filed on July 03, 2003.

Information Disclosure Statement

The IDS(s) filed March 08, 2004, March 29, 2004 and August 18, 2004 have been received and is signed and considered, a copy of the PTO 1449 is attached to the following document.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim the phrase "substantially modify" has not been defined in the claims or the specification of the present application. The claim states that the exposure does not substantially modify the low density lipoprotein, however the applicants have not defined or explained clearly the extent of substantial modification of the mentioned low density lipoprotein.

In **claim 3** the phrase "substantially similar" is not defined in the claim or the specification of the present application. The applicants state that the particle derivative has physical, chemical or biological properties that are substantially similar to naturally formed pre-beta high density lipoprotein; however the applicants do not explain the manner in which the mentioned properties are substantially similar.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Dass.

Claims 1-24 cite a particle derivative of high-density lipoprotein comprising apolipoprotein A-1 and phospholipids. The claims continue to explain a process of preparing the mentioned product and therefore are considered to be product by process claims. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-

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process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Dass discloses a particle derivative of high-density lipoprotein comprising apolipoprotein A-1 and phospholipids (table 1, page 167). Thus Dass teaches all the elements of **claims 1-24** and these claims are anticipated under 35 USC 102(b).

Claims 1-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Tricerri et al.

Claims 1-24 cite a particle derivative of high-density lipoprotein comprising apolipoprotein A-1 and phospholipids. The claims continue to explain a process of preparing the mentioned product and therefore are considered to be product by process claims. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Tricerri et al. disclose a particle derivative of high-density lipoprotein comprising apolipoprotein A-1 and phospholipids (methods, pages 188-190). Thus Tricerri et al. teach all the elements of **claims 1-24** and these claims are anticipated under 35 USC 102(b).

Claims 1-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Tricerri et al.

Claims 1-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Ito et al.

Claims 1-24 cite a particle derivative of high-density lipoprotein comprising apolipoprotein A-1 and phospholipids. The claims continue to explain a process of preparing the mentioned product and therefore are considered to be product by process claims.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Ito et al. disclose a particle derivative of high-density lipoprotein comprising apolipoprotein A-1 and phospholipids (materials and methods, page 895). Thus Ito et al. teach all the elements of **claims 1-24** and these claims are anticipated under 35 USC 102(b).

Conclusion

No claims are allowed.

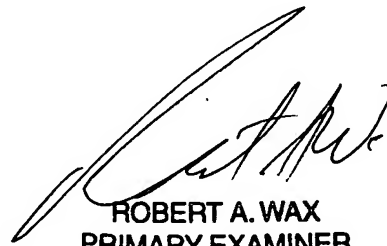
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert B Mondesi
Patent Examiner
Group 1653



ROBERT A. WAX
PRIMARY EXAMINER
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